



Plasmid DNA Capabilities

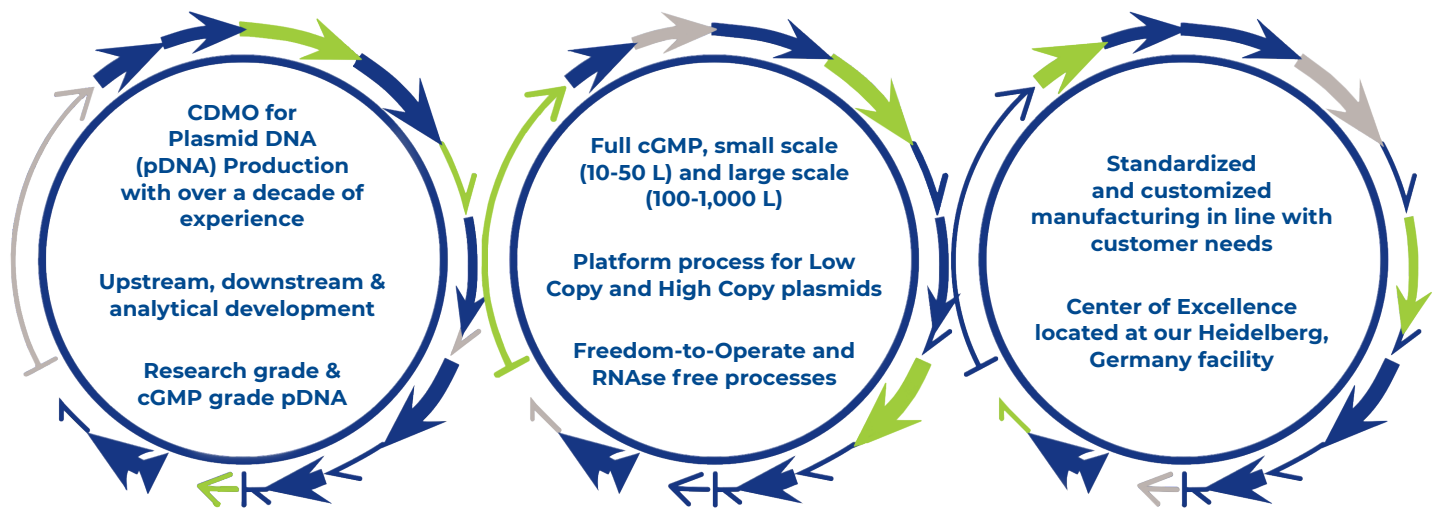
AGC Biologics is able to supply plasmid DNA (pDNA) in all grades and quantities, and for various applications. It has been used for many years in the manufacturing of DNA adjuvants and vaccines, as well as a starting material for RNA drugs and cell-free protein expression platforms. More recently, pDNA has become critical element for gene therapy applications, including Adeno-associated virus (AAV) and Lenti virus (LVV)-based therapies.

AGC Biologic's facility in Heidelberg, Germany has been manufacturing pDNA for **more than 10 years**. Our experience includes both clinical and commercial pDNA manufacturing. We have expanded

our capabilities in extending services in hosts and plasmids (low and high copy pDNA expression systems) via a large toolbox in process development with scales of 1 L to 10 L for pDNA. These processes can be scaled up to 50 L, 100 L, 500 L or 1,000 L cGMP manufacturing.

We also offer a fast platform approach for smaller pDNA amounts via a small-scale line, with scales of 10 L to 50 L. This can be used for producing transfer plasmid for in-house applications, **packaging plasmids for AAV and LVV applications**, and as linearized starting material for Messenger RNA (mRNA) manufacturing.

Plasmid Production



Plasmid DNA for direct vaccines, gene therapy, RNA drugs, etc.



Cell-line development or transfer of cell line to AGC Biologics



Establishment and validation of analytical methods for pDNA



Upstream process development and optimization



Optimization of alkaline cell-lysis on client's construct



Full cGMP, small scale (10-50 L) and large scale (100-1000 L)